UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MARIA ROBINSON,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION H- 20-03760
	§	
ETHICON, INC. and JOHNSON & JOHNSON,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court is defendants Ethicon, Inc., and Johnson & Johnson's (collectively, "Ethicon") motion to exclude certain opinions and testimony of plaintiff Maria Robinson's regulatory expert Peggy Pence. Dkt. 129. After considering the motion, response, reply, and applicable law, the court is of the opinion that the motion to exclude should be GRANTED IN PART and DENIED IN PART.

I. BACKGROUND

In October 2011, Robinson had a surgery to implant a medical device called the TVT-Obturator ("TVT-O"), which is a pelvic mesh product designed to relieve stress urinary incontinence ("SUI"). Dkt. 1 (short-form complaint); Dkt. 63-1 (long-form complaint). Robinson alleges she has suffered life altering injuries as a result of the implant and has undergone multiple removal surgeries. Dkt. 142. Consequently, she sued Ethicon, asserting numerous claims. Dkts. 1, 63. After extensive litigation, including multi-district litigation ("MDL") proceedings and a remand to this court, Robinson's remaining claims are failure to warn and negligent misrepresentation. *See* Dkt. 159.

Pence is a regulatory expert who Robinson retained to opine about Ethicon's regulatory responsibilities as the manufacturer of TVT-O. Dkt. 129, Ex. 1 at 8. Pence has "more than 40 years of experience in the research and development of traditional pharmaceuticals, biotechnology-derived therapeutics (biopharmaceuticals), and medical devices, including in vitro devices." *Id.* at 3. Pence states that "Ethicon knew early on that the TVT mesh has many characteristics that could lead to adverse outcomes for patients, including that the mesh had frayed edges, lost particles, could deconstruct, deform and rope. *Id.* at 52. Her main opinions are as follows:

> (1) Ethicon failed to conduct appropriate testing of the TVT-O System.
> (2) The TVT-O System was misbranded due to failure to warn and false or misleading labeling.
> (3) The TVT-O System labeling was inadequate and thus did not support adequate consenting of patients,
> (4) The TVT-O was misbranded due to failure to meet the postmarket vigilance standard of care.

See Dkt. 129; *see also* Dkt. 129, Ex. 1 at 58, 103, 104, 112, 133.[1]

Ethicon notes that the MDL court already granted the motion to exclude opinion #4, but it asserts that the court reserved ruling on certain arguments relating to opinions 1 and 3 and did not fully address Ethicon's arguments relating to opinion #2.[2] *Id.* It seeks exclusion of the remaining three opinions for the following reasons: (1) Pence's opinions about pre-market testing are unreliable because she does not apply an objective standard and has not surveyed the body of

[1] For the purposes of the instant motion, the court has used Ethicon's characterizations of Pence's opinions, which are not laid out exactly like they are in Pence's report. *See* Dkt. 129, Ex. 1 (listing five opinions rather than four). Robinson bases her briefing on the four categories discussed by Ethicon. *See* Dkt. 129.

[2] Ethicon asserts that Pence is not qualified to offer her opinions, but it acknowledges that the MDL court already overruled most of its objections to Pence's qualifications; it reasserts these already overruled objections in the instant briefing only to preserve error. Dkt. 129.

clinical data in the medical literature; (2) Pence's misbranding and labeling opinions are unreliable because she applied the incorrect legal standard by declaring physicians' knowledge irrelevant to what should be included in the TVT-O Instructions for Use ("IFU"); (3) Pence should not be permitted to testify about the device being "misbranded" or "adulterated" because these are legal terms of art; (4) Pence should not be permitted to testify about informed consent because she applied no reliable methodology to understand the knowledge of the intended users of the product—pelvic floor surgeons—and has no knowledge about the Texas legal standard for informed consent; and (5) Pence's informed consent opinions are irrelevant because there are no informed consent claims at issue because only the doctor had to be warned under Texas law. *Id.*

Robinson argues that each of Ethicon's complaints about Pence's opinions go to the weight of her testimony rather than admissibility. Dkt. 140. She contends that (1) Pence relied on the Global Harmonization Task Force ("GHTF") guidelines (an objective standard) for her opinions about testing, which Pence noted in her report and discussed in depth during her deposition testimony; (2) Ethicon conflates the requirements of the learned intermediary doctrine with the requirements of *Daubert* admissibility when making its labeling and misbranding arguments; (3) it is up to the jury to determine whether the warnings to physicians were adequate; and (4) Ethicon is using an "out-of-context snippet of testimony for the proposition that Dr. Pence has declared physicians' knowledge irrelevant to what should be in the IFU" when the "record shows Dr. Pence has considered what physicians knew about the risks of the product," and even if physicians know about a risk, they may not know about the incidence or percentage of that risk. *Id.*

The motion to exclude aspects of Pence's testimony not considered by the MDL is now ripe for disposition.

II. LEGAL STANDARD

The U.S. Supreme Court acknowledged in *Daubert v. Merrell Dow Pharmaceuticals* that Federal Rule of Evidence 702 serves as the proper standard for determining the admissibility of expert testimony. 509 U.S. 579, 597-98, 113 S. Ct. 2786 (1993). The party offering expert testimony has the burden to prove by a preponderance of the evidence that the proffered testimony satisfies the admissibility requirements of Federal Rule of Evidence 702. *Mathis v. Exxon Corp.*, 302 F.3d 448, 460 (5th Cir. 2002). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Under *Daubert*, a trial court acts as a "gatekeeper," making a "preliminary assessment of whether the reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93; *see also Kumho Tire v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167 (1999); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243-44 (5th Cir. 2002). *Daubert* and its principles apply to both scientific and non-scientific expert testimony. *Kumho Tire*, 526 U.S. at 147. Experts need not be highly qualified to testify, and differences in expertise go to the weight of the testimony, rather than admissibility. *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009). Nonetheless, courts need not admit testimony that is based purely on the *ipse dixit* of the expert. *GE v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512 (1997); *Moore v. Ashland Chem. Inc.,* 151 F.3d 269, 276 (5th Cir. 1998).

In addition to being qualified, an expert's methodology for developing the basis of his or her opinion must be reliable. *Daubert*, 509 U.S. at 592-93; *Moore*, 151 F.3d at 276. "The expert's assurances that he [or she] has utilized generally accepted scientific methodology is insufficient." *Moore*, 151 F.3d at 276. Even if the expert is qualified and the basis of her opinion is reliable, the underlying methodology must have also been correctly applied to the case's particular facts for her testimony to be relevant. *Daubert*, 509 U.S. at 593; *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007). The party proffering expert testimony has the burden of establishing by a preponderance of the evidence that the challenged expert testimony is admissible. See Fed. R. Evid. 104(a); *Moore*, 151 F.3d at 276. The proponent does not have to demonstrate that the testimony is correct, only that the expert is qualified, and that the testimony is relevant and reliable. *Moore*, 151 F.3d at 276.

III. ANALYSIS

A. Pre-Market Testing

The first challenged opinion is that Ethicon did not properly test the TVT-O. Pence opines that Ethicon failed to investigate concerns about foreign body reaction and chronic inflammation, mesh degradation, cytotoxicity, chronic infection leading to chronic inflammation, loss of pore size of the mesh, and potential carcinogenicity. Dkt. 129, Ex. 1 at 58. Pence asserts that Ethicon "failed to perform testing that was critical to learning the long-term safety of the TVT/TVT-O permanent implant." *Id.*

Ethicon moves for the court to exclude this opinion about its premarket testing because it is not reliable. Dkt. 129. Ethicon contends that Pence provides a conclusory citation to the GHTF guidelines as a foundation for her opinions, but she does not actually apply the guidelines. *Id.* It points out that in her deposition testimony, Pence agreed that under the GHTF guidelines, clinical

data can be in the form of scientific medical literature as well as clinical studies and that a manufacturer can evaluate the literature for similar devices to determine if there is a favorable benefit-risk ratio that make pre-market clinical studies unnecessary. *Id.* (citing Dkt. 129, Ex. 5 at 75–76). Additionally, Ethicon questions the reliability of Pence's testimony about its testing because she did not survey the entire body of clinical data or note that the FDA had placed all surgical mesh in Class II based on its history of safe and effective use. *Id.*

Robinson points out that Pence is a "forty-year veteran of the regulatory process" and "experienced from the manufacturer's perspective" and thus "is uniquely qualified to opine about the factors and considerations that go into a reasonable manufacturers' decisions as to what testing is necessary and appropriate." Dkt. 140. She notes that under Rule 702, "an expert's experience may be 'the predominant, if not sole, basis for a great deal of reliable expert testimony.'" *Id.* (quoting Fed. R. Evid. 702, advisory comm. notes). She then points to specific examples in Pence's deposition testimony where she explains what the GHTF guidelines require and why it is her opinion that Ethicon did not follow these standards. *Id.* As far as the medical literature, Robinson argues that while Ethicon takes issue with how much medical literature Pence considered, it does not point to sources that she should have yet failed to consider. *Id.*

In reply, Ethicon cites an opinion by the MDL court in the *Lewis* case in which the court found that Pence's opinion that additional testing should have been done was grounded only in her professional opinion and not reliable. Dkt. 146 (citing *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig. (Lewis)*, No. 2:12-MD-02327, 2014 WL 186872, at *18 (S.D. W. Va. Jan, 15, 2014)). Ethicon concedes that Pence changed her report after *Lewis* to include a reference to the GHTF guidelines, but it contends that she "finessed her reports to gerrymander the FDA out and

replace it with [GHTF]." *Id.* It reasserts that Pence did not apply the GHTF guidelines and that her report is thus wholly unreliable. *Id.*

The court has reviewed the report and cited portions of deposition testimony. In the report, Pence states that she "conducted background research, constructed theories, tested those theories against the information I reviewed and the industry standards of which I am aware through my knowledge, experience, and training, analyzed my findings, and communicated my conclusions herein." Dkt. 129, Ex. 1. One of the industry standards upon which she relied is the GHTF guidelines; she provides background information about these guidelines in her report. *Id.* She also discusses her application of the guidelines in her deposition. Dkt. 140, Ex. A.

The court finds that, in light of Pence's extensive experience and her assertion that she applied the industry standards, her discussion of the standards in her report, and her deposition testimony, Robinson has shown that Pence's methodology is reliable. Any concerns that she merely gerrymandered the FDA out of her report and substituted it with GHTF without actually applying those factors can be explored during cross examination. As far as Ethicon's contention that Pence did not review the entire body of clinical data, Pence asserts that she based her conclusions on her experience and reviewed medical literature. *See* Dkt. 140, Ex. A at 527 ("I reviewed the medical and scientific literature that was relevant."). If she failed to review certain pertinent literature, this also can be brought out during cross examination. Ethicon's arguments go to the weight and not the admissibility of Pence's testimony. Ethicon's motion to exclude Pence's testimony about pre-market testing as unreliable is DENIED.

B. Application of Legal Standard to the IFU

The next challenged opinion relates to misbranding or mislabeling. Pence opines that the TVT-O IFU document was inadequate because it did not include various risks. *See* Dkt. 129,

Ex. 1. Ethicon asserts that her opinion about the adequacy of the IFU is unreliable and suffers a "fatal flaw" because Pence did not consider what physicians already knew, and under Texas law, it is the physicians who must be adequately warned. Dkt. 129. Ethicon points to a statement Pence made during her deposition that the knowledge of physicians was irrelevant to what should be included in the IFU because there are standards and regulations governing what should be in the label. *Id.* (citing Dkt. 129, Ex. 6 (Pence Dep.)). Ethicon provided the court with Texas cases in which courts have stated that there is no duty to warn the learned intermediary if the dangers associated with a product are common knowledge. *Id.* Ethicon also cites the FDA's guidelines that indicate there is no need to warn about commonly known hazards. *Id.* (citing 21 C.F.R. § 801.109(c)). It asserts that expert opinions based on incorrect legal standards are inadmissible and that allowing Pence to testify about a standard that is different than the standard the jury will apply will confuse the jury. *Id.*

Robinson argues that Ethicon is conflating the requirements of the learned intermediary doctrine with the requirements of *Daubert* admissibility. Dkt. 140. She notes that the determination of whether the warning is adequate is a question for the jury, and Ethicon points to no requirement under Texas law that a regulatory expert must poll physicians to determine if a particular risk is common knowledge prior to opining about the adequacy of a warning. *Id.*

In reply, Ethicon asserts that Pence was clear in her deposition that physicians' knowledge of frequency and severity of side effects was irrelevant to her opinion of what should be in the IFU. Dkt. 146. Ethicon asserts that the FDA's regulations specifically allow information commonly known to a device's users to be excluded from the IFU. *Id.* (citing 21 C.F.R. § 801.109(c)). Moreover, Ethicon argues that Pence's opinions on what should be in the IFU do not comport with the law to be applied in this case. *Id.*

The regulation Ethicon cites to states:

> (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: ***Provided, however***, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

21 C.F.R. § 801.109(c) (emphasis in original). It thus does, as Ethicon asserts, provide a limited exception to inclusion in the IFU if information is "commonly known to practitioners." The regulation provides a method for submitting a proposal to omit such information to the Commissioner for an opinion. Thus, theoretically, a warning could be adequate even if it does not warn of certain side effects if the side effects are common knowledge to physicians licensed to use the device.

The court will briefly consider some of the warnings that *are* in the TVT-O label to provide context to this discussion. The label warns that "[a]cceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds." Dkt. 129-1 at 72 (quoting the label). It warns that the procedure to implant "should be performed with care to avoid large vessels, nerves, bladder and bowel." *Id.* It also warns that "[a]ttention to patient anatomy and correct passage of the device will minimize risks" and that the physician should "[o]bserve for any symptoms or signs [of post-operative bleeding]

before releasing the patient from the hospital." *Id.* These are just a few of the warnings that are included that one would presume are common knowledge to a physician licensed to use the device.

Here are a few of the allegedly known adverse reactions that Pence opines should have been included in the label and were not: venous thrombosis, vaginal perforation, vaginal scarring, shrinkage due to contraction and scarring, urinary problems including urethral injury, voiding dysfunction, worsening or recurrence of incontinence, and death. *See id.* at 76–77. Certainly, some of the items Pence believes should have been in the label were also in medical literature, and it is possible that a lot of physicians knew about this literature. However, where pharmaceutical companies should draw the line as to what is "commonly known" is certainly not clear when one considers the types of warnings that were included in the label; it is thus helpful that the regulation allows them to obtain an opinion from the Commissioner.

Ethicon does not point to any specific items that Pence opines should have been included on the label that were actually common knowledge of Texas physicians and could have been left off. Instead, it asks the court to wholesale exclude Pence's opinion about what the regulations require and what in her expertise should have been in the label as unreliable because she may not have considered—given her statement about it not being relevant to what the regulations require—what Texas physicians may have already known. The court agrees with Robinson that it is up to the jury to determine whether the warning was adequate to warn physicians, and Ethicon may ask its witnesses—and Pence—if the items Pence opines should have been included in the label are common knowledge of physicians. Pence's methodology is not unreliable simply because she did not poll physicians. This is an issue for cross examination, not exclusion.

Before concluding this section, the court addresses Ethicon's contention that the jury will be confused if the court allows Pence to testify about a standard that is different than the standard

the court will ask the jury to apply. There are always multiple standards to apply, and this case has an additional layer because the jury will also be considering regulations. Trials are not necessarily simple, but the lawyers and the court must present the issues to the jury in a way in which it can understand what standards it is required to apply when. If Ethicon fears the jury will be confused because Pence is talking about regulatory standards and the jury must determine whether the physician was adequately warned notwithstanding the regulations Pence refers to, then it needs to explain the distinctions to the jury in a way that non-lawyers can understand. While certainly *Daubert* tasks the court with making sure the information provided to the jury is helpful, it does not require the court to make sure the jury does not have to decipher complex information. Some cases are just complex, and juries decipher complex information and apply different laws and standards all the time. The attorneys are in charge of explaining the complexities of their cases to the jury, and the jury charge must explain the standards to be applied. In the court's experience, juries are more than capable of sorting out the information presented to them.

Ethicon's motion to exclude Pence's testimony about the adequacy of the IFU is DENIED.

C. Legal Terms of Art

Ethicon next argues that Pence should be excluded from testifying about the device being "misbranded" or "adulterated" because these are legal terms of art. Dkt. 129. Its example is that an expert may not testify that a product is "defective." *Id.* (citing an opinion from the MDL court that relied on *Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008)). It notes that the MDL court already ruled that the experts may not "'usurp the jury's fact-finding function by allowing [state-of-mind and legal-conclusion] testimony.'" *Id.* (citing Dkt. 129, EX. 2 at 11).

Robinson asserts that Ethicon provides no case law for the proposition that a regulatory expert should be excluded from using these terms that are defined in the regulations if it is within the scope of her qualifications. Dkt. 140. Ethicon does not address this in its reply. *See* Dkt. 146.

The Fifth Circuit case Ethicon relies on is *Estate of Sowell v. United States*, 198 F.3d 169 (5th Cir. 1999). In *Estate of Sowell*, the Fifth Circuit affirmed the district court, which had prohibited an expert from answering hypothetical questions about what a "reasonable fiduciary" would do in a situation identical to the facts of the case. 198 F.3d at 171. The Government argued that allowing him to opine about "reasonable cause" "would convey to the jury a legal conclusion." *Id.* The district court allowed the expert to testify about "the definition and general standards of conduct of a fiduciary," but it did not allow him to testify about whether the conduct in the case was reasonable. *Id.* The Fifth Circuit agreed that the trial court acted within its "wide discretion" when not allowing the expert to testify about whether the estate was acting reasonably because "the only issue for the jury in [the] case to decide" was whether the Estate had acted reasonably. *Id.* at 171–72.

In the Fifth Circuit, an expert witness may give an opinion on "an 'ultimate issue' of fact" if the expert is qualified to do so, but the witness may not "offer conclusions of law." *United States v. Oti*, 872 F.3d 678, 691 (5th Cir. 2017). The expert is not permitted to "'merely tell the jury what result to reach.'" *Id.* at 692 (quoting *Salas v. Carpenter*, 980 F.2d 299, 305 n.4 (5th Cir. 1992)).

The remaining claims in this case are failure to warn and negligent misrepresentation. Under *Estate of Sowell*, Pence may not testify about whether Ethicon failed to warn physicians or negligently misrepresented its product. However, she is a regulatory expert and may testify about the regulatory process. Under 21 U.S.C. § 352, a drug or device is "misbranded" if its label is false or misleading, among other requirements. Under 21 U.S.C. § 351, a drug or device is deemed

"adulterated" if, among other reasons, a device is not in conformity with performance standards. The court finds that Pence's expertise regarding the branding regulations will be helpful to the jury, and she is permitted to testify about what the regulations require and Ethicon's conduct with regard to the regulations. *Cf. In re Suboxone Antitrust Litig.*, MDL No. 2445, Civ. A. No. 16-5073, 2020 WL 6887885 (E.D. Penn. Nov. 24, 2020) ("Numerous courts have found that 'the testimony of regulatory experts on the reasonableness of a pharmaceutical company's conduct in light of the complex nature of the FDA framework is helpful to a jury.'" (collecting cases)). This testimony is not invading the province of the jury. However, she cannot take the final step of opining that the product was "misbranded" or "adulterated," as these are impermissible legal conclusions. *See id.* ("However, the next two paragraphs," which conclude that a pharmaceutical company's claims about its product were "false and misleading" under the regulations and that she would have advised the company that such claims "would violate FDA requirements," "cross the line into an inadmissible legal opinion."); *see also In re Davol, Inc. Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509 & 2:18-md-2846, 2021 WL 3286439, at *8 (S.D. Ohio Aug. 1, 2021) (prohibiting regulatory expert from offering opinion that a product was "misbranded"). Ethicon's motion with regard to the use of "misbranded" and "adulterated" is GRANTED IN PART; Pence may not make the final legal conclusions in her testimony, but she may use the terms "adulterated" and "misbranded" to demonstrate to the jury what the regulations require.

D. Informed Consent Opinions

Pence opines that in her "professional opinion, professional and patient labeling did not support adequate consenting of patients for TVT-O implantation and, accordingly, patients underwent TVT-O implantation without the benefit of true informed consent." Dkt. 129, Ex. 1.

She contends that because of deficiencies in the labeling and patient brochures, "physicians and patients lacked information critical to a frank discussion of the potential benefits and also the potential risks of TVT-O implantation in the patient." *Id.*

Ethicon contends that Pence is not qualified to testify about whether the IFUs are adequate for doctors to obtain informed consent of their patients as she is not a surgeon or doctor and that she also did not use reliable methodology to understand the knowledge of pelvic floor surgeons. Dkt. 129. It notes that Pence did not even consider the Texas informed consent standard, which is outlined in a statute. *Id.* (citing Tex. Civ. Prac. & Rem. Code § 74.102; 25 Tex. Admin. Code § 601.1). Ethicon additionally asserts that Pence's informed consent opinions are irrelevant because Pence's opinions about the patient's consent are intertwined with her opinions about the adequacy of the label, and it is immaterial under Texas law whether the physician would have conveyed additional risks to the patient. *Id.* Essentially, it asserts that informed consent is not at issue. *Id.*

Robinson asserts that Ethicon's argument "completely misses the point because Dr. Pence's informed consent opinion centers on the fact that patients . . . cannot properly give informed consent because physicians . . . have not been adequately warned under the learned intermediary doctrine." Dkt. 140. She reiterates that Pence's methodology of determining whether the IFU is adequate is reliable because she did not have to consider common knowledge of physicians, but that she did rely on the opinions of Dr. Meng Chen and internal Ethicon documents in reaching her conclusions about the IFU as well as deposition testimony of other physicians about what they knew about the risks of the product. *Id.*

Ethicon argues in reply that Pence was clear in her deposition that physicians' knowledge was irrelevant to her opinion about what should be in the IFU. Dkt. 146. It asserts that "Pence

has expressly admitted that she does not know what knowledge physicians had and, in her analysis of the warnings, she plainly did not take that knowledge into account." *Id.*

First, the court believes Pence is qualified to discuss whether the IFUs provide sufficient information to the learned intermediary (surgeons) even though she is not a surgeon or doctor. She has vast experience in the industry and has advised manufacturers on the adequacy of proposed medical device labeling. Dkt. 129, Ex. 1. She has "reviewed or contributed substantially to the development of product labeling, including not only adverse reaction content but also contraindications and warnings, nonclinical toxicology and clinical studies information, and product use instructions." *Id.* She is not a medical doctor, but she has a Ph.D. in Toxicology with a Pharmacology minor. *Id.* She has more than 40 years of experience in research and development of pharmaceuticals and medical devices. *Id.* To prepare the report, she reviewed depositions of various physicians and the Ethicon documents related to this case, and her experience in the industry makes her particularly well suited to offer an opinion about whether the IFU is adequate. She is qualified.

That being said, there is an issue about her opinion that patients, rather than physician, were not adequately warned because of the Learned Intermediary Doctrine.[3] Pence cannot testify about whether patients underwent implantation without true informed consent because under Texas law the manufacturer only has a duty to inform the learned intermediary, who must then provide the warnings to patients.[4] Thus, because Ethicon's duty under Texas law is to adequately

[3] The court discussed the Learned Intermediary Doctrine in its order on Ethicon's motion for summary judgment, which can be found at docket entry 159.

[4] The doctor who performed Robinson's TVT-O implant surgery testified that he expected the manufacturer to put any adverse events it knows of into the IFU and that standard practice is to provide the information in the IFU to patients. *See* Dkt. 143, Ex. P at 139–40.

inform the physician, who then should pass on the appropriate warning to patients, the adequacy of any warnings provided directly to the patient are not at issue and thus not relevant except to the extent physicians also received those warnings.

Ethicon takes issue with Pence's methodology in formulating her opinion that the labeling was insufficient for physicians to discuss risks with patients and obtain informed consent, mainly because she said in her deposition that physicians' knowledge does not impact her opinion about what should go into the IFU. As discussed in Part III.B, *supra*, there was no need for Pence to poll all physicians in Texas to formulate a reliable opinion about what warnings should go in the IFU. She may testify as to whether, in her opinion, the IFU provided sufficient warnings to physicians, and her methodology of relying not only on her regulatory experience but considering the testimony of physicians who worked for Ethicon, scientific studies, and internal Ethicon documents is reliable.[5] Ethicon may, of course, point out that Robinson did not survey all Texas physicians about the warnings when it cross examines her at trial; the fact that she did not goes to the weight of her testimony, not its admissibility.

Ethicon's motion to exclude Pence's testimony about informed consent in GRANTED IN PART AND DENIED IN PART. She cannot testify that the IFU was inadequate as a direct warning to patients, but she may testify about the adequacy of the warning to physicians, who provide warnings to patients to receive informed consent.

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[5] Ethicon insists in its reply that "***nowhere*** in her Rule 26 Reports does Pence give any indication whatsoever that she has taken physicians' knowledge into account in her methodology." Dkt. 146. However, she discusses depositions of Ethicon executives who are also physicians. And she notes that Dr. Piet Hinoul, whose deposition she reviewed, "agreed that all these complications should be reflected in the TVT labeling" and that "Dr. [Axel] Arnaud agreed it was very important for the company to communicate the known risks to physicians so they would know what they are and to make sure the risks are communicated to patients." *Id.* She also relied heavily on the testimony of Ethicon Medical Director Dr. Robinson. *Id.*

IV. CONCLUSION

Ethicon's motion to exclude Pence's testimony (Dkt. 129) is GRANTED IN PART and DENIED IN PART. It is GRANTED in that Pence may not testify that professional and patient labeling did not support adequate consenting of patients to the extent the warnings were directly to patients. Additionally, it is GRANTED in that Pence may not draw final legal conclusions about the product in question being "misbranded" or "adulterated" in her testimony, but she may use the terms to demonstrate to the jury what the regulations require. It is otherwise DENIED.

Signed at Houston, Texas on March 2, 2022.

Gray H. Miller
Senior United States District Judge